

## ERRATA and PROPOSAL

### ERRATA

#### Maryland Register

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## Errata

### COMAR 10.34.39

At 42:26 Md. R. 1633 (December 28, 2015), column 2, line 27 from the bottom:

For: adopt new Regulations **.01—.05** under a new chapter,

**COMAR**

Read: adopt new Regulations **.01—.04** under a new chapter,

**COMAR**

At 42:26 Md. R. 1634 (December 28, 2015), column 2, line 15 from the bottom:

For: **.05 Record Keeping.**

Read: **.04 Record Keeping.**

[16-01-29]

### PROPOSAL

#### Maryland Register

Issue Date: December 28, 2015

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## Title 10

## DEPARTMENT OF HEALTH AND MENTAL HYGIENE

### Subtitle 34 BOARD OF PHARMACY

#### *10.34.39 Pharmacist Administration of Self-Administered Drugs*

Authority: Health Occupations Article, §§12-101, 12-102(b), and 12-509, Annotated Code of Maryland

#### Notice of Proposed Action

[15-405-P]

The Secretary of Health and Mental Hygiene proposes to adopt new Regulations **.01 — .05** under a new chapter, **COMAR 10.34.39 Pharmacist Administration of Self-Administered Drugs**. This action was considered by the Board of Pharmacy at a public meeting held October 21, 2015 notice of which was given by publication on the Board of Pharmacy website, <http://dhmh.maryland.gov/pharmacy/SitePages/Home.aspx>, from September 21, 2015 — October 21, 2015, pursuant to the General Provisions Article, §3-302(c), Annotated Code of Maryland.

#### Statement of Purpose

The purpose of this action is to require a pharmacist, that administers self-administered drugs to a patient that have been prescribed by an authorized prescriber, to have an active certification in basic cardiopulmonary resuscitation obtained through in-person classroom instruction. The proposal also requires that the pharmacist attest that the pharmacist has the appropriate training in administration of self-administered drugs that consists of the administration of ear drops; eye drops; inhalation therapies; intramuscular injections; intranasal therapies; subcutaneous injections; and topical therapies. The pharmacist will be further required to document administration of a self-administered drug in

the patient record which shall include the name of the drug; dosage administered; site of administration; date and time of administration; and any instructions provided to the patient.

#### **Comparison to Federal Standards**

There is no corresponding federal standard to this proposed action.

#### **Estimate of Economic Impact**

The proposed action has no economic impact.

#### **Economic Impact on Small Businesses**

The proposed action has minimal or no economic impact on small businesses.

#### **Impact on Individuals with Disabilities**

The proposed action has no impact on individuals with disabilities.

#### **Opportunity for Public Comment**

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to [dhmh.regs@maryland.gov](mailto:dhmh.regs@maryland.gov), or fax to 410-767-6483. Comments will be accepted through January 27, 2016. A public hearing has not been scheduled.

#### **.01 Scope.**

*This chapter does not limit or affect the right of an individual to practice a health occupation that the individual is authorized to practice.*

#### **.02 Definitions.**

*A. In this chapter, the following terms have the meanings indicated.*

*B. Terms Defined.*

*(1) "Board" means the State Board of Pharmacy.*

*(2) "Pharmacist" means an individual who practices pharmacy regardless of the location where the activities of practice are performed.*

*(3) "Pharmacy" means an establishment holding a permit under Health Occupations Article, §12-401, Annotated Code of Maryland.*

*(4) "Pharmacy Experiential Program" means a program under the American Council on Pharmacy Education.*

*(5) Practice Pharmacy.*

*(a) "Practice pharmacy" means to engage in any of the following activities:*

*(i) Providing pharmaceutical care;*

*(ii) Compounding, dispensing, or distributing prescription drugs or devices;*

*(iii) Compounding or dispensing nonprescription drugs or devices;*

*(iv) Monitoring prescriptions and nonprescription drugs or devices;*

*(v) Providing information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices;*

*(vi) Identifying and appraising problems concerning the use or monitoring of therapy with drugs or devices;*

*(vii) Acting within the parameters of a therapy management contract, as provided under Health Occupations Article, Subtitle 6A, Annotated Code of Maryland; or*

*(viii) Administering vaccinations in accordance with Health Occupations Article, §12-508, Annotated Code of Maryland or self-administered drugs in accordance with Health Occupations Article, §12-509, Annotated Code of Maryland.*

*(ix) Delegating a pharmacy act to a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program;*

*(x) Supervising a delegated pharmacy act performed by a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program; or*

*(xi) Providing drug therapy management in accordance with Health-General Article, §19-713.6, Annotated Code of Maryland.*

*(b) "Practice pharmacy" does not include the operations of a person who holds a permit issued under Health Occupations Article, §12-602, Annotated Code of Maryland.*

*(6) "Registered pharmacy intern" means an individual who is registered with the Board to practice pharmacy under the direct supervision of a pharmacist.*

*(7) Self-Administered Drug.*

*(a) "Self-administered drug" means a drug that is regularly administered by the patient for whom the drug is prescribed or by an individual who is not otherwise authorized to administer drugs under Health Occupations Article, §12-509, Annotated Code of Maryland.*

*(b) "Self-administered drug" includes:*

*(i) Eye drops;*

- (ii) A drug that is administered by an intramuscular injection or a subcutaneous injection;
- (iii) Ear drops;
- (iv) Inhalation therapies;
- (v) Intranasal therapies; and
- (vi) Topical therapies.

**.03 Requirements to Administer Self-Administered Drugs.**

A. A licensed pharmacist shall attest that the pharmacist has the appropriate training in administration of self-administered drugs that consists of instruction on:

- (1) Ear drops;
- (2) Eye drops;
- (3) Inhalation therapies;
- (4) Intramuscular injections;
- (5) Intranasal therapies;
- (6) Subcutaneous injections; and
- (7) Topical therapies.

B. A licensed pharmacist shall possess an active certification in basic cardiopulmonary resuscitation obtained through in-person classroom instruction.

C. A licensed pharmacist, certified under Health Occupations Article, §12-508, Annotated Code of Maryland, is deemed to have satisfied the training requirements in this chapter.

D. A licensed pharmacist may administer a self-administered drug in accordance with a prescription.

E. A pharmacy student in a Pharmacy Experiential Program or a registered pharmacy intern, may administer a self-administered drug under direct supervision of a licensed pharmacist who meets the requirements in §A or B of this regulation.

**.05 Record Keeping.**

A. The pharmacist shall document in the patient record the administration of a self-administered drug that includes the following information:

- (1) Name of the drug;
- (2) Dosage administered;
- (3) Site of administration;
- (4) Date and time of administration; and
- (5) Any instructions provided to the patient.

B. The patient record shall be maintained for 5 years, unless otherwise required by law, and be:

- (1) Readily retrievable; and
- (2) Made available on the request of the Board.

VAN T. MITCHELL  
Secretary of Health and Mental Hygiene